

K964840

**Summary of Safety and Effectiveness
Compliance with 513 (i) of the Federal Food, Drug and Cosmetic
Act**

October 16, 1996

1. General Provisions

Common/Usual Name: Beam Block Trays or Shadow Trays

Proprietary Name: Beam Block Trays

Applicant Name and Address:

Aktina Medical Physics Corporation
360 North Route 9W
Congers, NY 10920

2. Name of Predicate Devices:

(1) MED-TEC, Inc. Beam Blocking Trays (K944315)

3. Classification

This device is classified as a class II device according to 21 CFR 892.5050

4. Performance Standards

Performance standards for sheath introducers have not been established by the FDA under Section 514 of the Food, Drug and Cosmetic Act.

5. Intended Use and Device Description

This device is intended to be used as a support for beam shaping or beam defining blocks in the delivery of external beam (photon) radiation therapy.

6. Biocompatibility

No issues of biocompatibility are raised with regard to this device.

7. Summary of Substantial Equivalence

This device is similar in design and construction, utilizes the identical materials, and has the same intended use and performance

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Any statement made in conjunction with this submission regarding substantial equivalence to any other product only relates to whether the product can be lawfully marketed without pre-market approval or reclassification and is not to be interpreted as an admission or used as evidence in patent infringement litigation. As the Commissioner of the FDA has indicated, "...a determination of substantial equivalence under the Federal Food, Drug, and Cosmetic Act relates to the fact that the product can be lawfully marketed without pre-market approval or reclassification. This determination is not intended to have any bearing whatsoever on the resolution of patent infringement suits." 42 Fed. Reg. 42,520 et seq. (1977).

characteristics to the predicate devices. No new issues of safety or effectiveness are introduced by using this device.